

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Gazyva (obinutuzumab)

DRUG.00062

Override(s)	Approval Duration
Prior Authorization	1 year

APPROVAL CRITERIA

- I. Requests for Gazyva (obinutuzumab) may be approved as treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma when the following criteria are met:
 - A. As first-line treatment in individuals without del (17p) mutation, when used in combination with chlorambucil or bendamustine; **OR**
 - B. As first-line, single agent in individuals who are frail or with del (17p) mutation; **OR**
 - C. As a single agent for the treatment of relapsed/refractory disease without del (17p) mutation.

OR

- II. Requests for Gazyva (obinutuzumab) may be approved as a treatment of follicular lymphoma when used as a component of *one* of the following combination chemotherapy regimens (A., B. or C. below) *and* as monotherapy, for up to 24 months or until disease progression, following the listed combination therapy regimens:
 - A. Cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP regimen); **OR**
 - B. Cyclophosphamide, vincristine, and prednisone (CVP regimen); **OR**
 - C. Bendamustine.

Gazyva (obinutuzumab) **may not be approved** for the following:

- A. When the above criteria are not met and for all other indications, including but not limited to diffuse large B-cell lymphoma and mantle-cell lymphoma.

Note: Gazyva (obinutuzumab) has black box warnings for hepatitis B reactivation and progressive multifocal leukoencephalopathy (PML). Hepatitis B Virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur with Gazyva. Individuals should be screened for HBV prior to treatment initiation and those with HBV monitored during and after treatment. Therapy should be discontinued in the event of HBV reactivation. PML, including fatal PML, can occur with Gazyva therapy. Individual should be

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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premedicated with a glucocorticoid, acetaminophen and an antihistamine for infusion reaction prophylaxis.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Bauer K, Rancea M, Roloff V, et al. Rituximab, ofatumumab and other monoclonal anti-CD20 antibodies for chronic lymphocytic leukaemia. *Cochrane Database Syst Rev.* 2012;(11):CD008079.
2. Gazyva [Product Information]. South San Francisco, CA. Genentech, Inc.; November 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125486s017s018lbl.pdf. Accessed on October 9, 2018.
3. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information visit the NCCN website: <http://www.nccn.org>. Accessed on October 08, 2018.
4. NCCN Clinical Practice Guidelines in Oncology®. © 2018 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 9, 2018.
 - B-Cell Lymphomas (V5.2018). October 02, 2018.
 - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (V2.2019). October 04, 2018.
5. Obinutuzumab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated October 05, 2018. Available at: <http://www.micromedexsolutions.com>. Accessed on October 10, 2018.
6. Obinutuzumab Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised April 06, 2016. Accessed on October 10, 2018.

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